DITTA CONTRIBUTION TO IMDRF STAKEHOLDER FORUM

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JIRA Executive Director

IMDRF Stakeholder Forum
Kyoto, 16 Sep. 2015
Key Topics

Updates about DITTA
DITTA views on current work items
Outcomes on DITTA Workshop on Standard
DITTA: Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association

Vice-Chair 2015-2016

Official NGO

JIRA

Chair 2015-2016

Vice-Chair 2015-2016

Formal Liaison

WHO

IMED\n
Kmdica

ITAC

MEDEC

COCIR

China Association for Medical Devices Industry

abimed

World Bank

ITAC Health

MITA

Medical Imaging & Technology Alliance

abimed

Medical Imaging & Technology Alliance
DITTA: 9 WORKING GROUPS

DITTA Working Groups

- RPS
- SaMD
- MDSAP
- UDI
- Standard
- ENVI
- WB
- WHO
- GRP

IMDRF
RECOMMENDATIONS
FROM DITTA TO IMDRF
DITTA believes the time is right to set longer-term goals to guide the organization.

- The MC also discussed IMDRF strategic plan to identify its direction for the coming years to better coordinate its activities and allocate its limited resources. The MC will finalize the plan in Kyoto meeting in September 2015.

DITTA would appreciate the MCs openness in discussing your vision with industry.

- Look forward to constructive and substantive discussions with IMDRF

DITTA requests that the MC create a formal opportunity for industry to contribute to MC decision-making prior to final decision.

- Look forward to constructive and substantive discussions with IMDRF
DITTA VIEWS ON CURRENT WORK ITEMS
DITTA initially proposed this IMDRF work item and appreciates the current active engagement in the IMDRF QMS guidance as well as the previous publications (definitions & risk categorization).

– DITTA believes that the IMDRF QMS guidance can benefit much more by the following consideration:
  • DITTA believes the guidance should carefully keep the scope of ISO 13485.
  • DITTA appreciates it if its global implementation will actively be considered.

– DITTA believes that the next activity of the IMDRF SaMD work group is very important for the upcoming worldwide regulatory convergence:
  • DITTA believes that IMDRF should follow the results of the most recent stakeholders survey.
  • In future IMDRF SaMD work items, risk management should embrace the goals of security and networking of medical devices!
Industry remains committed to MDSAP & favors further QMS convergence.

Current Status

- Implementation of IMDRF MDSAP in member jurisdictions is not formalized and DITTA would like to raise the adoption in member jurisdictions.
- It is unclear how to expand the MDSAP Guidance Documents into non IMDRF member countries.
  - We still have the same concerns from the past – that a particular country won’t “accept” the results and will do their own audit.

Harmonized Requirements for QMS & ISO 13485 Revision.

- Current MDSAP covers multilateral audit, Industry expects convergence with QMS requirements.
- Continue to ensure that MDSAP complements the ISO 13485 revision process as originally intended to achieve a harmonized standard among IMDRF members.
DITTA appreciates the recent engagement with industry.

For Business Case analyzing;

– Technology Option Scoring
  • The Management Committee should understand that the scoring exercise is based on technical assessment, not cost. It was made very clear that implementation considerations, e.g. cost are out of scope of the current scoring. Industry assumes that there will be a final scoring that incorporates cost, infrastructure, required, etc. Thus, one solution scoring well, e.g. HL7 RPS, does not mean it makes sense from a cost/benefit perspective.

– Cost Consideration
  • Cost considerations are a significant aspect of the assessment in addition to scoring the technology options. Cost for each of the solutions should be determined prior to the MC making their decision. The MC making a decision without fully understanding the cost of each technology option makes no sense.

– Implementation Guide
  • The RPS WG should be tasked with developing an implementation guide after the MC has made their decision, which should include high-level milestones for implementation work.
DITTA appreciated the opportunity to comment on the Exchange Criteria and Report Form.

Outcome of NCAR has very big impact to industries activities in post market phase, because the differences of reportable criteria or contents of incident report are existing in each jurisdiction, we need to support them in each jurisdiction.

- The NCAR WG needs to share more information on the activities that have taken place to date and future plans.
- Increase of industry engagement in further development of NCAR
OUTCOMES ON DITTA WORKSHOP ON STANDARD ON 14TH SEPTEMBER 2015
OUTCOMES ON DITTA WORKSHOPS ON STANDARD

Attendance: XXX participants

Summary:

Presentations:
Questions on

To be completed post workshop
DITTA REMAINS SUPPORTIVE OF IMDRF WORK AND ALWAYS READY TO CONTRIBUTE!

THANK YOU FOR YOUR SUPPORT

www.globalditta.org